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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/670,046	09/24/2003	Frank Hardt	RO0233US.CON (#90568)	5022
28672 7590 01/25/2010 D. PETER HOCHBERG CO. L.P.A. 1940 EAST 6TH STREET CLEVELAND, OH 44114			EXAMINER DESAI, ANISH P	
			ART UNIT 1794	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/670,046	Applicant(s) HARDT ET AL.	
	Examiner ANISH DESAI	Art Unit 1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/04/09.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 10-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-5, 7 and 12 is/are allowed.
- 6) ☒ Claim(s) 6, 10, 11 and 13-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's arguments in response to the Office action dated 08/03/09 have been fully considered.
2. Applicant has incorporated subject matter of claim 8 in claim 1, and deleted polyurethane and polyethylene from the scope of the matrix layer composition.
3. In view of applicant's amendment, new 35 USC Section 112-first paragraph rejections are made.
4. In view of applicant's amendment, the 35 USC Section 103(a) rejections based on Kreckel et al. (US 5,244,677) in view of Lindquist et al. (US 3,665,918) and Horstmann et al. (US 5,716,636), and as evidenced by Allen Jr. et al. (US 4,650,817) as applied to claims 1-6 and 8 are withdrawn. None of the aforementioned reference discloses matrix layer as presently claimed in claim 1.
5. A new 35 USC Section 103 (a) rejections to new claim 13 is made.

Allowable Subject Matter

6. Claims 1-5, 7, and 12 are allowed over the prior art of record.
7. The following is an examiner's statement of reasons for allowance:
8. **The closest prior art to claim 1 is Kreckel et al. (US 5,244,677) and Montgomery et al. (US 4,576,817).**

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9. Kreckel discloses a transdermal drug delivery device (bandage strips) (adhesive die-cut article) having a drug formulation that is stored in a punched out cavity of foam material such as polyethylene foam layer 18 (see abstract, column 6 lines 65-68 to column 7 lines 1-15). The polyethylene foam layer 18 of Kreckel is equated to the matrix layer.

10. However, Kreckel does not teach or suggest a specific composition of the matrix layer i.e. matrix layer comprising "a natural or synthetic polymer selected from the group consisting of polyacrylates, polypropylenes...copolymers" as now presently claimed in claim 1.

11. Montgomery discloses absorbent material such as bandages (abstract). Further, at column 1 lines 29-35, Montgomery discloses that materials such as cellulose and its derivatives, polyester, nylon, etc. have been fabricated in the form of woven fibers, foams etc.

12. However, absent hindsight, there is no reason or motivation to combine the aforementioned teaching of Montgomery with the disclosure of Kreckel (i.e. polyethylene foam being equated to matrix) to render obvious claim limitation of matrix layer comprises "a natural or synthetic polymer selected from the group consisting of polyacrylates, polypropylenes...copolymers" as presently claimed in claim 1. Accordingly, the aforementioned claims are allowed over the prior art of record.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claims 10, 11, and 13-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

14. Claims 10 and 13 recite "gel". While there is support in the specification to recite "gel-like" (see claim 6 as originally filed), there is no support to recite "gel".

15. Claims 11 and 13 recite "powdery preparation". There is no support in the specification to recite "powdery preparation". While there is support to recite "powdery materials" (see claim 6 as originally filed), there is no support to recite "preparation".

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

16. Claims 6, 11, and 13-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

17. Regarding claim 6, said claim recites "gel-like", it is submitted that the phrases such as "like" renders said recitation ambiguous because it is not clear as to what is meant by "gel-like".

18. As to applicant's response against the Examiner's rejection of the term "gel-like", the Examiner submits that while it is true that the term "gel-like" is supported and appears in the parent literature, the question is not whether said term is supported or appears in the prior art; rather the question is what does this term encompass ? **The Examiner submits that if applicant clarifies on the record what is intended to be meant by the term "gel-like", the Examiner will then reconsider the rejection.**

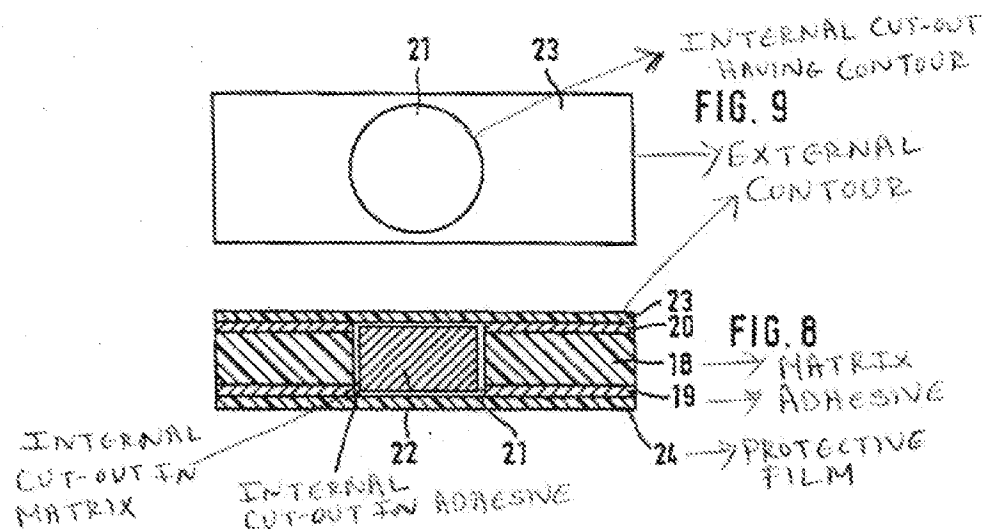
19. Regarding claim 11 and 13, said claims recite "powdery preparation", it is unclear as to what is meant by "powdery preparation".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

20. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kreckel et al. (US 5,244,677) in view of Lindquist et al. (US 3,665,918), Horstmann et al. (US 5,716,636), and Carduck et al. (US 4,415,124), and further as evidenced by Allen Jr. et al. (US 4,650,817).



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21. With respect to claim 13, as set forth above in the Drawing reproduced from Kreckel, it is submitted that Kreckel discloses a transdermal drug delivery device (bandage strips) (equated to applicant's adhesive die-cut article) having a drug formulation that is stored in a punched out cavity of foam material such as polyethylene foam layer 18 (see abstract, column 6 lines 65-68 to column 7 lines 1-15). Additionally, as shown above in Figures 8 and 9 above, the adhesive die-cut article of Kreckel has an external contour which comprises adhesive layer 19 with an internal cut-out having a contour, wherein the external contour of the adhesive die-cut article has no common point with the contour of the internal cut-out as claimed.

22. Further, the die-cut article as set forth above in Figure 9 of Kreckel has a layer of foam 18 having punched out reservoir (equated to the matrix layer) having an internal cut-out which is congruent with the internal cut-out in the adhesive layer 19. Additionally, a protective film 24 (equated to covering film) (column 7 lines 10-15) covers the composite of matrix layer, adhesive layer, and the internal cut-out is provided in the article of Kreckel.

23. Additionally, at column 6 lines 67-68 to column 7 lines 1-5, Kreckel discloses "In FIGS. 8 and 9...for a transdermal delivery of low-viscous micro-emulsion containing the particular drugs. These micro-emulsions are contained in a material piece (22) of absorbent material placed in a punched out reservoir (21)...closed cells." This

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disclosure of Kreckel is interpreted to read on “wherein the internal cut-out is filled with filler material containing pharmaceutical active ingredient” as claimed.

24. Regarding claim 13, the difference between the claimed invention and the prior art of Kreckel is that Kreckel is silent as to teaching the foam layer (matrix layer) being a compacted material, specific pharmaceutical active ingredient, and the filler material as presently claimed.

25. However, Lindquist discloses a conformable adhesive sheet that has improved conformability and splitting resistance and can be used as surgical drape or bandage (abstract). The adhesive tape of Lindquist comprises compressed foam web (abstract). The compressed foam web of Lindquist is interpreted to meet claim requirement of “matrix layer being a compacted material” as presently claimed in claim 1. At column 2 lines 60-75 to column 3 lines 1-5, Lindquist provides motivation to use compressed foam (matrix layer being a compacted material). Specifically, Lindquist discloses that the use of compressed foam assures the presence of sufficient material to meet tensile strength requirement and still provides desired thinness of the web (column 2 lines 62-63). Additionally the disclosure of Lindquist at column 3 lines 1-25 with respect to the compression of foam is interpreted that such compression improves splitting resistance of the adhesive tape.

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26. While it is noted that the disclosure of compression of foam in Lindquist's invention is primarily drawn to the polyurethane foam, whereas the primary reference of Kreckel discloses the use of polyethylene foam, the Examiner submits that at column 9 lines 55-65, Lindquist generally discloses that his inventive concept (i.e. compression of foam) has also applicability to functionally equivalent thermoplastic foams. The reference of Allen, Jr. et al. (US 4,650,817) is relied upon as an evidence to show that in adhesive bandage dressing art, polyethylene foam and polyurethane foams are functionally equivalent in formation of backing. Specifically, Allen discloses skin compatible adhesive composition that can be used in fabricating wound dressings (abstract and column 1 lines 10-20). At column 10 lines 25-35, Allen discloses use of foam backing such as polyethylene or polyurethane as backing to form his adhesive tape.

27. It is noted that the primary reference of Kreckel discloses use of a matrix layer in formation of his/her adhesive tape, but Kreckel does not teach that the matrix layer being compacted material. Lindquist discloses adhesive tape that is useful in the same field as that of Kreckel, namely adhesive tape in medical field (e.g. as dressings). Further, Lindquist provides motivation to use compacted material, specifically the use of matrix layer being a compacted material provides sufficient tensile strength and also provides enhanced peel and splitting resistance (column 1 lines 10-15).

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28. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the matrix layer of Kreckel as being compacted material, motivated by the desire to provide sufficient tensile strength and also provides enhanced peel and splitting resistance to the device of Kreckel.

29. Additionally, with respect to claim 13, Kreckel as modified by Lindquist is silent as to teaching the specific pharmaceutical active ingredient as presently claimed.

30. However, Horstmann discloses a transdermal therapeutic system comprising active substance acetylsalicylic acid (abstract).

31. It is noted that Kreckel as modified by Lindquist is silent as to teaching a specific drug. Therefore, based on the collective disclosure of Kreckel as modified by Lindquist and Horstmann, it would have been obvious to select the pharmaceutical active ingredient such as acetylsalicylic acid as taught by Horstmann and used in the invention of Kreckel, because selection of a known material based on its suitability for its intended use establishes *prima facie* obviousness.

32. Kreckel as modified by Lindquist and Horstmann are silent as to teaching the specific filler as presently claimed.

33. However, Carduck discloses a method for the production of micropowders (abstract). Additionally, at column 5 lines 59-65, Carduck discloses that the powders of

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his invention can be used as vehicles (equated to applicant's filler being powdery preparation) for drugs in the pharmacy. Additionally, given that specification and claims do not define or give any example of what constitutes fusible material, the powder of Carduck is fusible material.

34. It would have been obvious to select the powders as fillers as taught by Carduck in the invention of Kreckel so as to use said powders as vehicle, since it has been held that selection of a known material based on its suitability for its intended use establishes *prima facie* obviousness. Further, given that the size distribution of the powder effects the rate of dissolution (col.6, lines 2-4), it would have been obvious to select powders as fillers in order to control the release of the drug.

Response to Arguments

35. As to applicant's arguments on page 9 against new claim 13 that Kreckel does not teach claim limitation of the filler material being gel, powdery preparation and a fusible material, the Examiner submits that as set forth in this Office action, Carduck et al. (US 4,415,124) is relied upon to teach filler material is powdery preparation and fusible material as presently claimed.

Conclusion

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36. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US Patent 4,393,048 to Mason, Jr. et al. discloses protective gel compositions for wounds.

37. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

38. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

39. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANISH DESAI whose telephone number is (571)272-6467. The examiner can normally be reached on Monday-Friday, 9:00AM-5:30PM.

40. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Callie Shosho can be reached on 571-272-1123. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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41. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/A. D./

Examiner, Art Unit 1794

/Callie E. Shosho/

Supervisory Patent Examiner, Art Unit 1794